DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 6, 2015

J DENTAL CARE S.r.l.
% Maurizio Pantaleoni
CEO
ISEMED S.r.l.
Via A. Bonetti 3/a
Imola, BO 40026
ITALY

Re: K143142
Trade/Device Name: JDentalCare Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 28, 2015
Received: September 30, 2015

Dear Maurizio Pantaleoni,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143142

Device Name
JDentalCare® implant system

Indications for Use *(Describe)*
JDentalCare® implant system is intended for surgical placement in the upper or lower jaw.
JDentalCare® implant system is comprised of dental implant fixtures and prosthetic devices.
JDentalCare® implant system provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla.
JDentalCare® implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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I - 510(k) SUMMARY

The 510(k) Summary is provided below

510(k) Summary for the K143142
JDENTALCARE Implant System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: J DENTAL CARE S.r.l. is located at:
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Summary Preparation Date: October 20, 2014

2. Names

Device Name:	JDentalCare®Implant System
Primary Classification Name:	Endosseous dental implant
Primary Product Code:	DZE
Regulation number:	872.3640
CLASS:	II
Secondary Classification Name:	Endosseous dental implant abutment
Secondary Product Code:	NHA

3. Predicate Device

The JDentalCare®Implant Systems is substantially equivalent to the following predicate device:

Applicant	Device name	510(k) Number	Product code
Nobel Biocare USA LLC	Nobel Active Internal Connection Implant	K071370	DZE NHA

Reference devices considered are listed below:

Applicant	Device name	510(k) Number	Product code
Nobel Biocare USA LLC	Nobel Active 3.0	K102436	DZE NHA
A.B. Dental Devices Limited	A.B Dental Devices	K051719	DZE
Implant Direct LLC	Legacy system Dental Implants With HA Coating	K073033	DZE

4. Device Description

JDentalCare®implant system is composed by a fixture and an abutment, joined together by a through screw (JDEvolution). In this case the connection is done through an internal hexagon. Abutments and accessories are exclusive for JDentalCare®implant system.
JDentalCare®implants are threaded, root-form dental implants, intended to provide a mean for prosthetic attachment in the rehabilitation of partial or total edentulism, in single tooth restorations or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures.
JDentalCare®implants are machined from grade 4 or grade 5 titanium and tapered. Their surface is treated with a double acid etched treatment.
JDentalCare®implants may be placed in the oral cavity using either a single stage surgical procedure or a two stage surgical procedure. If a single stage procedure is used, the implants may be placed anywhere in the upper or lower jaw where good initial stability can be obtained

In the following table there are the dimensions for all the JDENTALCARE Implants:

JDENTALCARE implant system : JDEvolution dental implant dimensions					
IMPLANT DIAMETER	**IMPLANT LENGTHS**				
3,25	8	10	11,5	13	15
3,7	8	10	11,5	13	15
4,3	8	10	11,5	13	15
5	8	10	11,5	13	15
6	8	10	11,5	13	15

Below a short description of all the abutments included in this submission:

HEALING ABUTMENT: it is used in the delayed loading technique (used when there is not a good primary stability of the bone) to close the implant connection for non-submerged healing. It helps the gum to heal properly. The abutment is screwed into the implant.

HEALING ABUTMENT BI COMPONENT: it is used in the delayed loading technique (used when there is not a good primary stability of the bone) to close the implant connection for non-submerged healing. It helps the gum to heal properly. The abutment is screwed into the implant with a screw.

TEMPORARY ABUTMENT (engaging / not engaging): Temporary Abutments are used for the fabrication of temporary screw-retained restorations. Engaging and non-engaging variants are used for single- and multiple-unit implant restorations, respectively

GP ABUTMENTS: is indicated for cemented temporary restorations of single and multiple implants. It can be modified with a drill or it can be used as definitive abutment.

STRAIGHT ABUTMENTS: it is indicated for cemented prosthesis of single or multiple units. Collar height can vary from 1mm to 4 mm depending on the height of soft tissues

ANATOMIC ABUTMENTS: it is indicated for cemented prosthesis of single or multiple units.
The anatomic abutment has an anatomical festoon preparation of the cervical margin that ensure lesser need of abutment preparation.

CONICAL ABUTMENT: is indicated for screwed-in prosthesis. Conical abutments are intended to be used only for multi-unit restorations, with not angulation correction.

BALL ABUTMENTS: it is indicated for overdentures with ball anchoring

EMI ABUTMENTS: it is indicated for overdentures with emispheric anchoring

5. Indications for Use

JDentalCare® implant system is intended for surgical placement in the upper or lower jaw.
JDentalCare® implant system is comprised of dental implant fixtures and prosthetic devices.
JDentalCare® implant system provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla.
JDentalCare® implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.

6. Performance data

Dimensions, materials and surface treatments are substantially equivalent to those of predicate devices. Also, J DENTALCARE performed the following tests on JDentalCare®implant system:

BIOCOMPATIBILITY according to ISO 10993-1:2010 Biological Evaluation of Medical Devices Part 1

- Cytotoxicity
- Intracutaneous reactivity
- Delayed Hypersensitivity
- Systemic Toxicity
- Bacterial Reverse Mutation

The results of all the reports listed above show that the JDentalCare®dental implants are:

- Not Cytotoxic
- Satisfying the requirements for intracutaneous reactivity test
- Not sensitizing
- Satisfying the requirements for systemic toxicity test
- Not Mutagenic

SURFACE VALIDATION TESTS

Surface treatment is performed on implants through a double acid treatment: first phase with fluoride acid etching, and a second phase of acid attack with a mixture of strong acids (solforic acid + chloridric acid). Then, there is a cleaning through a cool plasma

These tests, show the results of SEM and XPS analysis and the complete removal of materials (e.g. cutting oils or detergents) used during manufacturing process.

MECHANICAL TESTS

The Mechanical test were performed in compliance with “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” and “ISO 14801: 2007 - Dynamic fatigue test for endosseous dental implants”.

STERILIZATION AND PACKAGING SHELF LIFE

JDentalCare®implant system are sterilized with gamma ray sterilization to assure a SAL level of10^{-6}.

Shelf life is 5 years. The packaging and shelf life were tested and validated according to applicable international standards

7. Substantial Equivalence Discussion:

COMPARATIVE TABLE FOR IMPLANTS

The indications for use of the JDentalCare® implant system devices can be considered substantially equivalent to the identified predicate devices.
The material, shape, the dimensions and the connection are equivalent to that of the predicate devices as shown in the table below:

	JDENTALCARE Implant System Implants	**Predicate Devices**		
	JDEvolution (K143142)	**A.B Dental Devices (K051719)**	**Nobel Active (K071370) (K102436)**	**Implant Direct Legacy (K073033)**
Intended Use				
Intended Use	JDentalCare® implant system is intended for surgical placement in the upper or lower jaw. JDentalCare® implant system is comprised of dental implant fixtures and prosthetic devices. JDentalCare® implant system provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screw-retained or cemented restorations in mandible and maxilla. JDentalCare® implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	A.B. Dental Devices' implants are intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. Two-piece implants – **I1, I2, I2b & I5:** Two-stage implants - **I2, I2b & I5** implants: One-stage implants - **I1** One piece implants - **I6, I7** Implants for immediate loading when good primary stability is achieved and with appropriate occlusal loading **I2, I2b, I5, I6 & I7**	The NobelActive 3.0 mm implant is indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implant may be put into immediate function provided that stability requirements detailed in the manual are satisfied.	These implants are two-piece implants for single-stage or two-stage surgical procedures. The Legacy implants are intended for use in the mandible and maxilla, in support of single or multipleunit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.
Indication	Immediate load	I5: immediate loading	Immediate load	Immediate Load
Placement method	Dual or single stage surgery	I5: two stage implant	Dual or single stage surgery	Dual or single stage surgery
Design – Mechanical features				
Shape	Two pieces Tapered screw Internal Hexagon	I5: two pieces Tapered screw Internal Hexagon	Two pieces Tapered screw Internal Hexagon	Two pieces Tapered screw Internal Hexagon
Thread of the body	Double Thread outline: trapezoidal	I5: double thread outline: trapezoidal	Double Thread outline: trapezoidal	Double thread outline: trapezoidal
Materials	Titanium grade 4 Titanium grade 5 (for Ø 3,25mm)	Titanium alloy (Ti6AL-4V ELI) grade 5	Titanium grade 4	Titanium alloy (Ti6AL-4V ELI) (→grade 5)
Design - Dimensions				
Diameter (mm)	3.25/3.7/4.3/5/6	**I5**:3.5/3.75/4.2/4.5/5/6/7/8	3 /3.5/4.3/5	3.2/3.7/4.2/4.7/5.2/5.7 /7
Length	8/10/11.5/13/15	**I5**: 6/8/10/11.5/13/16	8.5/10/11.5/13/15/18	6/8/10/11.5/13/16
Design – Connection System				
Type	Internal Hexagon	I5: internal hexagon	internal Hexagon	Internal Hexagon
Packaging				
Package	plastic vial + blister	Double packaging	vial + blister	vial + blister
Sterile	Yes Gamma Radiation	Yes Method unknown	Yes Gamma Radiation	Yes Gamma Radiation

COMPARATIVE TABLE FOR ABUTMENTS:

The intended use for abutments of JDentalCare® implant system is identical to the predicate devices. The abutments have the same material composition and connection to the implants.
The main design features of the abutments are identical to the predicate devices as shown in the table below:

Features	JDENTALCARE® Implant System Abutments	Predicate Devices	
		Nobel Active (K102436)	A.B DENTAL (K051719)
Healing abutment Healing Abutment bicomponent	Available in 3 height: 3,5,7mm Material: Titanium	Available in 3 height: 3,5,7mm Material: Titanium	N/A
Temporary abutments	Temporary abutments non rotating / rotating models Material: Titanium	Temporary abutment non rotating and rotating Material: titanium or plastic	N/A
GP Abutment	GP abutment Height: 7 mm Material: titanium Abutment screw: included	Narrow profile abutments. Height: 7mm Material: titanium Abutment screw: included	N/A
Straight abutment	Straight abutment Collar height 1 – 2 – 3 – 4 mm Material: titanium	N/A	Anatomic abutment Collar height 1 – 2 – 3 – 4 mm Material: titanium
Anatomic Abutments	Anatomic abutments Collar height 1,5 – 3 Straight – angled 15°	Esthetic abutment Straight with Collar height 1,5 – 3 – 4,5 Angled 15°with Collar height 1,5 – 3 – 4,5	Anatomic angular abutment with shoulder
Conical Abutments	Conical abutments angle 0° - collar height 1,5 – 2 – 3 – 4 mm angle 17° - collar height 2,5 – 3,5 mm angle 30° - collar height 2,5 – 3,5 mm	Multi unit abutment Straight - collar height 1,5-2,5-3.5-4.5mm Angle 17° - collar height 2,5 - 3,5 mm Angle 30°- collar height 3,5 – 4,5 mm	N/A
Ball Abutments	Ball abutments Material: titanium	Ball Abutment . Material: titanium	N/A
Emi Abutments	Material: titanium	N/A	LOW Connector
Material	Titanium gr.5	Titanium (commercially pure)	Titanium gr.5
Sterility	Not Sterile	Sterile	Not Sterile

8. Applicable Standards:

The Family of JDentalCare®Implant Systems have been developed and tested according to the following international standards:

ASTM F67 - Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
ASTMF136 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications
ISO 14801: 2007 - Dynamic fatigue test for endosseous dental implants
ISO 11137-1 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical device
ASTM 1980 “Standard Guide For Accelerated Aging of Sterile Medical Devices Packages”.
ISO 10993-1:2010 Biological Evaluation of Medical Devices Part 1.

9. Conclusions

Based on technological characteristics (intended use, material used, dimensions and features) and performance data (mechanical tests, biocompatibility tests, sterilization and shelf life) included in this submission, the JDentalCare® implant system has been shown to be substantially equivalent to the listed predicate device